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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,945	05/14/2001	Clifton A. Alferness	1931-2	1454

996 7590 12/20/2002

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 12/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/855,945

Applicant(s)

ALFERNES ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) 16-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 41-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5. 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. The examiner affirms the change made to the restriction requirement, and would also like to make a correction to the election of species. The restriction/election of species is as follows:

I. Claims 1-15 and 39-57 drawn to an apparatus.

- a) Figure 2 is the embodiment of the first species
- b) Figure 9 is the embodiment of the second species
- c) Figure 10 is the embodiment of the third species

II. Claims 16-18 drawn to a method.

- a) Method of deploying a mitral valve annulus device within coronary sinus
- b) Method of determining the crossover point of the circumflex artery and coronary sinus

2. Applicant's election without traverse of Group I, claims 1-15 and 39-57 in Paper No. 8 is acknowledged. Applicant also elected claims 1-15 and 41-57 for being readable on both species of Figures 2 and 10. Claims 16-38 have been withdrawn for being directed to a non-elected invention of Group II (method). Claims 39 and 40 have been withdrawn for being directed to a non-elected species of species b (Figure 9). While examiner agrees that claims 1-15 and 41-57 are readable on Figures 2 and 10, applicant is still required to *elect one of the species* (Figure 2 or 10) under Group I in response to this office action.

### *Claim Objections*

3. Claims 51 and 55 are objected to because of the following informalities:

- a. Claim 51, line 1, --an-- should be inserted after "including".

b. Claim 55, line 1, --a-- should be inserted after “including”.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 3-11, 13-15, 41, 43-51 and 53-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Solem et al. (USPN 6,210,432 as cited in applicant's IDS).

Solem et al. discloses a device for treatment of mitral insufficiency with all the elements of claims 1, 41, 56 and 57. See Figures 2, 5, 6, 8 and 9 for an assembly for effecting the condition of a mitral valve annulus comprising a guide wire configured to be fed into the coronary sinus of the heart (column 4, lines 7-10) and a mitral valve annulus device (8) configured to be slidably received on the guide wire and advanced into the coronary sinus of the heart on the guide wire (column 4, lines 16-18) and that reshapes the mitral valve annulus when in the coronary sinus of the heart (Figures 8 and 9).

Claims 3-7, 43-47 and 56, see Figures 6-9. The device (8) is in the form of a stent, which has a bore (defined by Webster's II New Riverside University Dictionary as “the interior diameter of a hole, tube or cylinder”) at one end that continues into and is aligned with a cylindrical channel extending between the opposed ends of the device.

Claims 8 and 48, see column 4, lines 10-13 for guide wire formed of a material visible under X ray fluoroscopy.

Claims 9, 10, 49 and 50, see column 3, lines 37-39 for device being made from metal. A metal is inherently visible under X ray fluoroscopy to a certain degree.

Claims 11, 13, 14, 51, 53 and 54, see Figures 4-6 and columns 3-4, lines 47-3 for introducer (12). The proximal end of the introducer is the considered any portion proximal the distal-most region of engagement between the device and the introducer, and the distal end of the introducer is any portion of engagement between the device and the introducer (between 13 and 16). Therefore, the elongated introducer is configured to be slidingly received on the guide wire (column 4, lines 14-18) proximal the device. A releasable locking mechanism (16), including a locking pin and a curve in a stent wire defining locking groove, is configured to releasably lock the proximal end of the device to the distal end of the introducer.

Claims 15 and 55, see column 4, lines 6-7 for guide tube receiving guide wire, device and introducer.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2, 12, 42 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. in view of de Toledo et al. (USPN 4,830,023).

Solem et al. discloses a device for treatment of mitral insufficiency with all the elements of claims 1 and 41, but is silent to the guide wire and introducer being an elongated coil. de Toledo et al. teaches a guide wire being an elongate coil in order for it to have greater flexibility. See abstract. Because both the guide wire and introducer of Solem et al. are made of a wire (columns 3-4, lines 65-3) and require flexibility to travel through the venous system into to the coronary sinus, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of de Toledo et al. to modify the guide wire and introducer of Solem et al. such that they are elongated coils in order for them to have greater flexibility for the travel.

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 2, 8-12, 15, 41, 42, 48-52, 55 and 57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 9-15 of copending Application No. 09/855,946. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending

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application (09/855,946) discloses the same assembly having a guide wire, a mitral valve annulus device configured to be slidably received on the guide wire to reshape the mitral valve annulus within the coronary sinus.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

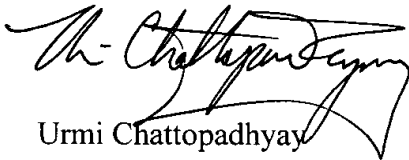
10. Claims 1, 11, 13, 41, 51, 53 and 57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of copending Application No. 09/751,271 in view of Solem et al. The copending application (09/751,271) discloses a mitral valve reconstructing system with all the elements of claims 1, 41 and 57 of the current application, but is silent to the system including a guide wire which is configured to be fed into the coronary sinus, and the mitral valve annulus device being configured to be slidably received on the guide wire. Solem et al. teaches a device and assembly for treating mitral valve insufficiency including a guide wire configured to be fed into the coronary sinus and wherein the device is configured to be slidably received on the guide wire in order to properly direct the device into the coronary sinus. See column 4, lines 6-19. It would have been obvious to one of ordinary skill in the art to look to the teachings of Solem et al. for the copending application (09/751,271) to include the guide wire in order for the device to be properly directed into the coronary sinus.

This is a provisional obviousness-type double patenting rejection.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738



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uc

December 16, 2002